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| EXAMINER |
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ROZANSKI, MICHAEL T

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| ART UNIT | PAPER NUMBER |
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3768

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06/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/826,960 | Applicant(s) ZHONG ET AL. | |
| | Examiner MICHAEL ROZANSKI | Art Unit 3768 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47, 54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47, 54 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7, 14-32, and 34-47 are rejected under 35 U.S.C. 102(e) as being anticipated by ***Ehnholm et al*** (US 6,975,896).

Ehnholm et al disclose a method of locating a medical device including mounting fiducials onto a surgical tool 52. The fiducials are filled with a liquid or gel of a fluorine compound that has a resonance frequency different from that of protons (col 4, lines 20-62). Images of the subject, which resonate frequencies from protons, are stored in image memory 42. Separately, reconstructed images of the fiducials, which are considered to be part of the surgical tool, are stored in image memory 64. A depiction of the tool or probe from a lookup table is appropriately positioned and rotated and superimposed on the proton image by a video processor 44 (col 5, lines 9-23). In

addition, the surgical tool to which fiducials are affixed may be a local MRI receive coil probe 80. Therefore, it is inherent that the claimed medical device comprising a receiver coil is disclosed (col 6, lines 12-27). It is noted that the MRI enhancement, as currently claimed, merely requires detection of a signal without making a relationship with the detecting of nuclei in line 10 of claim 1. Therefore, Ehnholm substantially discloses the receiver coil because it will inherently detect a signal.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-6 and 8-13 are rejected under 35 U.S.C. 102(e) as being unpatentable over ***Ehnholm et al*** in view of ***Chui*** (US Pub 2002/0101241).

Pacetti disclose using selected MRI detectable nuclei such as hydrogen and sodium, but do not specifically disclose using phosphor or iodine nuclei. It would have been obvious to one with ordinary skill in the art at the time the invention was to have incorporated such nuclei in order to permit improved MR imaging of a selected medical device and proximate body tissue under different conditions.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Ehnholm et al** as applied to claim 30 in further view of **Young et al** (US 5,817,017).

Ehnholm et al substantially discloses all features of the current invention but does not specifically disclose microporous material comprising a film or a foam. In the same field of endeavor, Young et al teach such a film (col. 8, lines 40-59). It would have been obvious to one with ordinary skill in the art at the time the invention was made to have incorporated the teaching of Young et al in order to enable a liquid to be encapsulated therein.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Pacetti** in view of **Toyoda et al** (US 4,713,722).

Pacetti discloses generating an MR image of a medical device, such as a guidewire, guide catheter, endovascular graft, biopsy needle, stent, or inflatable balloon catheter, and proximate body tissue, wherein the device has incorporated therein an imaging material comprising selected MRI detectable nuclei, such as hydrogen, phosphor, fluorine, or sodium nuclei (col. 2, lines 12-24; col. 6, lines 13-37; col. 6, line 65-col. 7, line 5; col. 9, lines 26-44). MRI images are taken including at least a portion of the medical device, which comprises a first image data, and including MRI detectable nuclei contained in the imaging material, which comprises a second image data, and are combined and displayed (col. 7, lines 8-29; col. 8, lines 4-37).

Pacetti does not specifically disclose that the first and second MRI processes uses the same frequency for excitation pulses, but different magnetic field strengths.

However, Toyoda et al teach that when imaging different nuclei such as fluorine, sodium, and phosphorus, it is beneficial to use a particular magnetic field strength for each type of nuclei (col 3, lines 18-30). It would have been obvious to the skilled artisan to use different field strengths when imaging the different types of nuclei in Pacetti, as taught by Toyoda et al, in order to permit more accurate diagnosis (col 3, lines 18-30).

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Pacetti** in view of **Schweighardt et al** (US 5,068,098).

Pacetti discloses generating an MR image of a medical device, such as a guidewire, guide catheter, endovascular graft, biopsy needle, stent, or inflatable balloon catheter, and proximate body tissue, wherein the device has incorporated therein an imaging material comprising selected MRI detectable nuclei, such as hydrogen, phosphor, fluorine, or sodium nuclei (col. 2, lines 12-24; col. 6, lines 13-37; col. 6, line 65-col. 7, line 5; col. 9, lines 26-44). MRI images are taken including at least a portion of the medical device, which comprises a first image data, and including MRI detectable nuclei contained in the imaging material, which comprises a second image data, and are combined and displayed (col. 7, lines 8-29; col. 8, lines 4-37).

Pacetti discloses incorporating fluorine into the medical device, but not specifically perfluoro-15-crown-5-ether. However, Schweighardt et al teach of a method for magnetic resonance imaging using perfluoro-15-crown-ether in order to provide enhanced diagnostic resolution (see Abstract). It would have been obvious to the

skilled artisan to use modify Pacetti to use the claimed compound, as taught by Schweighardt et al, in order to provide enhanced diagnostic resolution.

Response to Arguments

Applicant's arguments with respect to claims 1-47 and 54-55 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL ROZANSKI whose telephone number is (571)272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

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